IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA *ex rel.* **DEBBIE BURKE,**	*	
Plaintiff-Relator,	*	
v.	*	**Civil Case No. 16-3611-SAG**
ST. JUDE MEDICAL, INC.,	*	
Defendant.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Relator Debbie Burke ("Burke") filed a Motion for Award of Relator's Share, ECF 33, in which she requests 20% of the $27 million settlement between the United States and St. Jude Medical, Inc. ("St. Jude") pursuant to the *qui tam* relator's share provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730(d)(1). The United States (hereinafter referred to as "the Government") opposes Burke's motion and contends that she is not entitled to any share of its settlement proceeds, ECF 38. The issues have been fully briefed, ECF 33-1, ECF 38, ECF 39, and no hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2021). For the reasons stated below, Burke's Motion shall be granted in part and denied in part, and Burke shall receive 0.5% of the settlement proceeds.

I. FACTUAL AND PROCEDURAL BACKGROUND

On September 16, 2016, Burke received a surgically implanted St. Jude-manufactured pacemaker—specifically, a Unify Assura Cardiac Resynchronization Therapy Defibrillators ("CRT-D") device, model number CD3357-40C—at Johns Hopkins Hospital in Baltimore, Maryland. ECF 33-1 at 2. The cost of Burke's device was reimbursed by a private payer because she is not a Medicare beneficiary. ECF 1 ¶ 59. Roughly two weeks after Burke's procedure, on

October 11, 2016, the United States Food and Drug Administration ("FDA") issued a Class I recall of certain models of St. Jude's Fortify, Unify, and Assura Implantable Cardioverter Defibrillator ("ICD") and CRT-D devices. ECF 38-6. The FDA recall notice (hereinafter referred to as "FDA Notice") provided a full list of the affected models and specified that the recall was spurred by "reports of rapid battery failure caused by deposits of lithium (known as 'lithium clusters'), forming within the battery, and causing a short circuit." *Id.* The FDA Notice extended to specified device models manufactured from January, 2010 until May, 2015, and distributed from February, 2010 until October, 2016 (hereinafter referred to as "Recalled Devices"). *Id.*

Upon learning of the recall, Burke consulted St. Jude's online medical device database (hereinafter referred to as "St. Jude Device Database") to determine whether her device was subject to the advisory. ECF 1 ¶ 41. By inputting her device's unique model and serial numbers into the St. Jude Device Database, Burke determined that her pacemaker had been manufactured on May 12, 2015, and was among the Recalled Devices. *Id.* Burke subsequently spoke with her operating surgeon, who informed her that he had no knowledge of the defect, and that her device had been provided by a St. Jude representative for implantation on the day of her procedure. *Id.* ¶ 45. "In other words, neither her surgeon nor Johns Hopkins kept an inventory of these devices, they are provided directly by St. Jude as needed." ECF 33-1 at 3 (citing ECF 1 ¶ 45).

On November 2, 2016, Burke filed a *qui tam* complaint against St. Jude, alleging that it violated the FCA by submitting false claims to the Government for "implants of defective and faulty Fortify, Unify, and Assura ICD devices to the Medicare Program." ECF 1 ¶ 66. Burke's complaint included five key allegations. First, Burke alleged that at some point between 2010 and 2015, St. Jude became aware that Recalled Devices "had defective batteries that lead to premature battery depletion," ("PBD"). *Id.* ¶ 5. Second, she alleged that St. Jude "took corrective

manufacturing action to remedy" such defects in May, 2015. *Id.* ¶ 1. Third, she alleged that despite its actual knowledge of defects in Recalled Devices, St. Jude "did not take appropriate action to disclose the battery defect . . . to the FDA or healthcare providers." *Id.* ¶ 6. Fourth, she alleged that St. Jude continued to knowingly "promote and sell the defective devices until they were recalled by the FDA on October, 11, 2016 [*sic*]." *Id.* ¶ 6. And fifth, Burke alleged that although she was not herself a Medicare beneficiary, "it is reasonably foreseeable that Medicare paid for the defective versions of St. Jude's ICD devices." *Id.* ¶ 59.

After several extensions of time,[1] the Government elected to intervene in Burke's action for settlement purposes on July 7, 2021. ECF 28. The settlement agreement ("Settlement") entered into among the Government, St. Jude, and Burke, provided that St. Jude would pay $27 million to the Government to resolve allegations that it "submitted, or caused the submission of, false claims to Medicare, TRICARE . . . and the Federal Employee Health Benefits Program [('FEHBP')]." ECF 38 at 14. In relevant part, the Settlement covered claims arising from the following alleged course of conduct: (i) in 2013, St. Jude began developing a new battery design to prevent PBD in its ICD and CRT-D devices; (ii) in August, 2014, St. Jude requested expedited FDA permission for its new design; (iii) in its FDA submission, St. Jude falsely represented that "no serious injury, permanent harm or deaths" had been associated with PBD in its existing devices, despite actual knowledge to the contrary; (iv) the FDA approved St. Jude's new design on November 20, 2014, but did not request a voluntary recall of older devices because St. Jude's had misrepresented their risks; (v) St. Jude continued to distribute defective devices for implantation into Medicare, TriCare, and FEHBP patients after November 20, 2014—when the new design was approved—

[1] In January, 2017, the Government informed Burke of its belief that her action was precluded by the public disclosure bar, but that it did not presently intend to seek dismissal of her Complaint. ECF 38-1.

until October 10, 2016—the day prior to the FDA Notice; and (vi) it did so despite continuing to receive reports of serious incidents associated with PBD in older devices. ECF 38-3 at 2-3 (altered from original numbering). The Settlement specifically provided that the Government retained the right to oppose any award of shared proceeds to Burke. *Id.* On July 7, 2021, the Government and Burke filed a stipulation of dismissal, reserving the issue of relator share. ECF 30.

II. LEGAL STANDARDS

The FCA imposes civil liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). "To encourage the disclosure of fraud that might otherwise escape detection, the FCA permits private individuals, denominated as relators, to file *qui tam* actions on behalf of the government and collect a bounty from any recovery." *U.S. ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 39 (4th Cir. 2016) (citing § 3730(b)). To proceed with an FCA action as a private party, the "relator must file his or her complaint under seal and notify the government, who can either intervene or allow the relator to proceed alone." *Id.* Should the government elect to intervene, "it shall have the primary responsibility for prosecuting the action." § 3730(c).

Section 3730(e) enumerates several categories of actions that are barred under the FCA. As relevant here, the so-called "public disclosure bar," precludes actions if "substantially the same allegations or transactions as alleged in the . . . claim were publicly disclosed" in any of several specified sources unless "the person bringing the action is an original source of the information." § 3730(e)(4)(A)-(B). Cases subject to the public disclosure bar shall be dismissed unless dismissal is opposed by the government. *Id.*

The FCA entitles relators of successful claims prosecuted by the government to a share of the proceeds of the action or settlement. Generally, relators in an action led by the government shall "receive at least 15 percent but not more than 25 percent" of the proceeds of a settled claim, depending "upon the extent to which the person substantially contributed to the prosecution of the action." § 3730(d)(1). This standard range, however, is subject to exception for certain *qui tam* actions that are primarily based on public disclosures of information made by persons other than the relator. *Id.* Where a court finds this exception applicable, it may award a relator "no [] more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation." *Id.*

III. DISCUSSION

A. Public Disclosure Bar, § 3730(e)(4)(A)

Burke argues that she is entitled to a statutory payment within the 15%-25% range provided in § 3730(d)(1), and that within this range, a 20% award is appropriate. *See* ECF 33-1 at 10-11. The Government, for its part, contends that Burke's motion is foreclosed by § 3730(e)(4)(A), and that there is accordingly no need to analyze her award under § 3730(d)(1). The threshold question, then, is whether § 3730(e)(4)(A), which bars certain categories of *qui tam* complaints, is applicable to Burke's Motion for Award of Relator's Share.

"The public-disclosure bar aims 'to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits' in which a relator, instead of plowing new ground, attempts to free-ride by merely reiterating previously disclosed fraudulent acts." *U.S. ex rel. Beauchamp*, 816 F.3d at 43 (quoting *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 295 (2010)). In furtherance of these goals, the public disclosure bar, as amended in 2010, provides that:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed:
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> > (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

§ 3730(e)(4)(A). An original source, in turn, is defined as an individual who either voluntarily discloses information about the fraud to the government prior to the public disclosure, or one who "has knowledge that is independent of and materially adds" to the publicly disclosed allegations, which she provides to the government before filing suit. § 3730(4)(B).

The Government argues that because Burke's claim was subject to dismissal under the public disclosure bar, she is precluded from receiving any portion of the recovery from its intervention in, and successful resolution of, her suit. ECF 38 at 6-29. Put differently, the Government posits that because it could have sought dismissal of her action under the public disclosure bar, this Court cannot now authorize any award under § 3730(d)(1). The Government's argument is unpersuasive in light of its course of conduct in this case. The public disclosure bar is one of four statutorily enumerated actions that are barred under the FCA. *See* § 3730(e) ("Certain Actions Barred"). The section is not concerned with financial rewards to relators, but rather with who may speak for the United States for purposes of an FCA action. The FCA prescribes that operation of the public disclosure bar shall result in dismissal of the action, not the denial of a relator's share in any recovery from her claim. *See* § 3730(e)(4)(A) ("The court shall dismiss an action or claim under this section, unless opposed by the Government . . ."). At this juncture, this Court is unconcerned with whether the Government could have obtained dismissal

of Burke's claim; the fact is that the Government did not attempt to do so.[2] To the contrary, the Government elected to proceed with Burke's action, and ultimately obtained a $27 million settlement. *See* ECF 38-3. Having now done so, the Government urges that because the action it successfully prosecuted was improper from the start, Burke cannot receive any share of its recovery. The Government provides no binding precedent to support its assertion. *See* ECF 38 at 18 (citing *United States ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 106 (3d Cir. 2000); *United States ex rel. Prather v. Sprint Comms., Inc.*, 855 F.3d 985, 993 (9th Cir. 2017)). Moreover, this Court is persuaded that the Government's preferred interpretation would run afoul of the fundamental principle that all words in a statute must be given effect. *See PSINet, Inc. v. Chapman*, 362 F.3d 227, 232 (4th Cir. 2004) ("General principles of statutory construction require a court to construe all parts to have meaning and to reject constructions that render a term redundant."). Reading the public disclosure bar, § 3730(e)(4), to foreclose any award for relators whose actions are substantially similar to publicly disclosed allegations would render the second sentence of § 3730(d)(1)—which authorizes up to a 10% award to relators whose complaints are based primarily on information contained in public disclosures—redundant or meaningless. Absent Fourth Circuit caselaw to the contrary, this Court will decline the Government's invitation to assess Burke's motion under a section barring certain categories of actions, § 3730(e)(4), to the exclusion of the section that expressly governs "[a]wards to *qui tam* plaintiff[s]," § 3730(d). This Court will accordingly proceed to analyze Burke's motion under § 3730(d)(1).

[2] Indeed, the Government expressly asserted that although the public disclosure bar precluded Burke's claim, it did not intend to seek dismissal of her complaint. ECF 38-1.

B. Relator's Share Provisions, § 3730(d)(1)

Section 3730(d)(1) provides that relators of ultimately successful claims in which the government chose to intervene are entitled to specified shares of any settlement or judgment recovered by the government. Specifically, relators in an action led by the government shall "receive at least 15 percent but not more than 25 percent" of the proceeds of a settled claim, depending "upon the extent to which the person substantially contributed to the prosecution of the action." § 3730(d)(1). The minimum 15% statutory share is regarded by courts as a "finder's fee." *U.S. ex rel. Simmons v. Samsung Elecs. Am.*, Inc., 116 F. Supp. 3d 575, 577-78 (D. Md. 2015) (quoting *United States ex rel. Alderson v. Quorum Health Grp., Inc.*, 171 F. Supp. 2d 1323, 1331 (M.D. Fla. 2001)). "This 15% 'incentive compensation' is paid to a relator 'even if that person does nothing more than file the action in federal court.'" *Id.* (quoting *U.S. ex rel. Alderson*, 171 F. Supp. 2d at 1332 n.29 (internal quotation marks omitted)). By contrast, courts should award a percentage share above 15% and up to 25% in "those cases where the person carefully develops all the facts and supporting documentation necessary to make the case required by law, and where that person continues to play an active and constructive role in the litigation . . .". *U.S. ex rel. Alderson*, 171 F. Supp. 2d at 1332 (quoting 132 Cong. Rec. H9382-03 (Oct. 7, 1986) (statement of Rep. Berman))).

The standard range of awards is subject to a statutory exception for certain *qui tam* complaints that are based primarily on specific information in public disclosures. § 3730(d)(1). This exception applies to actions "which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from

the news media." *Id.* In such cases, "the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds" after considering the "significance of the information and the role of the person bringing the action in advancing the case to litigation." *Id.*

i. Statutory Range

Burke urges that her award is not subject to the 10% cap for actions based on publicly disclosed information and is instead properly analyzed under the general 15%-25% range. *See* ECF 33-1 at 10-11 (citing § 3730(d)(1)). Within that latter range, Burke contends that a 20% award is appropriate. *Id.* The Government argues that, assuming Burke is entitled to any share, it should be assessed within the 0%-10% range for complaints based primarily on public information. ECF 38 at 30. On this point, the Government carries the day. This Court concludes that Burke's action falls squarely into the category of actions "based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations in a[n] . . . administrative . . . report . . . or from the news media." § 3730(d)(1).

The Government identified eight sources, the composite of which it claims form the primary basis of Burke's complaint. These include: (i) Joe Carlson, *St. Jude Warns Batteries in up to 350,000 Defibrillators Worldwide Could Short Circuit and Fail*, MINNEAPOLIS STAR TRIB., Oct. 11, 2016, ECF 38-4; (ii) Joe Carlson, *St. Jude Stock Stable After Heart Device Battery Disclosure*, MINNEAPOLIS STAR TRIB., Oct. 12, 2016, ECF 38-5; (iii) the FDA Notice, ECF 38-6; (iv) the St. Jude 2015 Annual Report, ECF 38-7; (v) Sean D. Pokorney et al., *Novel Mechanism of Premature Battery Failure Due to Lithium Cluster Formation in Implantable Cardioverter-Defibrillators*, 11 HEARTH RHYTHM 12, 20190 (Dec. 2014) ("Duke Study"), ECF 38-8; (vi) an article in the *Journal of Internal Medicine* (2007), which is referenced in Burke's Complaint, *see* ECF 1 ¶ 60, but for which a citation is not provided; (vii) the FDA's Manufacturer and User

Facility Device Experience ("MAUDE") database, ECF 38 at 14; and (viii) the St. Jude Device Database, ECF 38-9.

First, this Court is satisfied that seven of the eight sources referenced by the Government constitute "administrative reports" or "news media" for purposes of the FCA. Burke does not contest that the newspaper articles, scholarly publications, FDA Notice, and annual report, all of which were published on public websites, constitute "news media." *See* ECF 39 at 10-11; *see also U.S. ex rel. Beauchamp*, 816 F.3d at 43 n.6. Similarly, the FDA Notice and the MAUDE Database—a publicly searchable FDA database containing manufacturer-submitted medical device reports— both meet the criterion of an administrative report. *See Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407 (2011) ("A 'report' is 'something that gives information' or a 'notification'" (internal citations omitted)). By contrast, this Court finds that the St. Jude Device Database cannot be considered "news media," even "in light of the ample precedent in favor of broad construction of the channels of public disclosure." *U.S. ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 2014 WL 4375638 *11 (E.D. Pa. 2014) (internal citations omitted). As far as this Court is aware, the St. Jude Device Database serves a single function: allowing users to determine whether their ICD or CRT-D device is subject to recall. *See* ECF 38-9. The tool appears to do no more than query whether the unique model and serial numbers inputted by the user appear within the population of Recalled Devices. *See id.*; ECF 39 at 13; ECF 38 at 14. It does not synthesize or analysis data, convey recent events, or exercise editorial discretion. The Government emphasizes that this tool is available to a large group of people, namely the 250,000 users affected by the recall. This fact alone, however, is not determinative. *See, e.g., U.S. ex rel. Customs Fraud Investigations* at *11 (E.D. Pa. 2014) (rejecting argument that eBay is a qualifying news media source). Moreover, the database's theoretically broad reach

is mitigated by the fact that its content is not made available wholesale; rather, search results are shared only with the single user that inputted her associated model and serial numbers.[3] The remaining seven sources cited by the Government will be considered as qualifying sources for purposes of this Court's analysis.

Second, this Court is satisfied that Burke's action is based primarily on allegations or transactions detailed in the seven qualifying sources provided by the Government. Taken together, the sources allege that: St. Jude became aware of PBD in its Recalled Devices prior to 2015, ECF 38-4, ECF 38-5, ECF 38-8; St. Jude remedied the defect in May, 2015, ECF 38-5; St. Jude did not sufficiently inform the FDA or healthcare providers of the defect, *id.*; St. Jude continued to distribute the Recalled Devices even after altering its battery design in new devices, ECF 38-6; and that Medicare is a substantial payor for CRT-D and ICD devices, ECF 1 ¶ 59 (citing the *Journal of Internal Medicine*). The allegations in Burke's Complaint are not merely similar to the information in these sources, they are actually derived from them. Indeed, in several instances, Burke expressly cites to these public disclosures to substantiate her claims. *See* ECF 1 ¶¶ 36-37 (citing FDA Notice to establish recall in October, 2016); *id.* ¶ 52 (citing Duke Study for proposition that "St. Jude obviously knew well before 2015 . . . that its batteries in its ICD devices were defective."); *id.* ¶ 55 (citing MAUDE database for the same assertion); *id.* ¶ 59 (citing *Journal of Internal Medicine* for assertion that Medicare likely paid for Recalled Devices); *id.* ¶ 61 (citing

[3] The cases cited by the Government do not alter this conclusion. In *U.S. ex rel. Customs Fraud Investigations, LLC*, 2014 WL 4375638 at *10, the court concluded that an online database containing shipping manifest information constituted "news media." In contrast to the St. Jude Device Database, however, that database "provide[d] data, analysis, and articles to many media outlets worldwide." *Id.* Moreover, the court in *U.S. ex rel. Hastings v. Wells Fargo Bank, Nat. Ass'n (Inc.)*, 2014 WL 3519129, at *12 (C.D. Cal. July 15, 2014) did not determine that a mass database of mortgage listings used by brokers constituted "news media." Rather, it merely concluded that knowledge obtained from such sources "cannot be described as firsthand" for purposes of the original source exception to the public disclosure bar. *Id.*

2015 St. Jude Annual Report for the same conclusion). Still other allegations in Burke's Complaint are not explicitly attributed to public disclosures but could not have been—nor does she claim that they are—derived from her independent knowledge or personal experiences. *See, e.g.*, *id.* at ¶ 48 (alleging that "on May 23, 2015 St. Jude took corrective action regarding the defective batteries."); *id.* at ¶ 51 (asserting that "St. Jude did not take appropriate action to disclose the battery defect and the corrective manufacturing actions to the FDA . . ."). [4] Finally, the allegation that St. Jude "continued to promote and sell the defective devices until they were recalled by the FDA on October 11, 2016," ECF 1 ¶ 6, appears to have been discovered through the FDA Notice, although subsequently confirmed by Burke's personal experiences. *See* ECF 1 ¶ 36 (stating that the FDA issued a Class I recall on October 11, 2016, and listing the recalled devices); *id.* ¶ 41 ("The particular device [Burke] received was . . . manufactured on May 12, 2015 and is one of the recalled devices based on the date of manufacturing."). Indeed, when information based on public disclosures is stripped from Burke's complaint, the only remaining allegations are relatively ancillary ones: that a Recalled Device was implanted into Burke by a healthcare professional who was not aware of its potential for PBD. *See* ECF 1 ¶ 59. Because there is no indication that the information in these sources was provided by Burke herself, *see* § 3730(d)(1), her potential award is limited to no more than 10% of the proceeds.

Burke contends that her action does not fall within the mandatory 10% cap for several reasons, each of which this Court finds unconvincing. First, Burke asserts that her allegations of fraud are not based on public information, but rather "from researching the particular device she

[4] Notably, these allegations, which are unattributed in the Complaint, are also specifically included in the public disclosures discussed herein. *See* ECF 38-5 (reporting that PBD in Recalled Devices "led to a design improvement to address the problem on May 23, 2015."); *id*. (asserting that St. Jude failed to timely disclose the issues).

received, together with questioning her surgeon regarding how the device had been acquired." ECF 33-1 at 10. It is true that Burke's Complaint includes personal information not contained in public disclosures: namely, that she herself received a Recalled Device, and that her operating physician was unaware of its risk for PBD. *See* ECF 1. These allegations, however, plainly do not constitute the primary basis of Burke's Complaint, nor could they. Absent information derived from public disclosures, Burke's Complaint would contain no allegations regarding the PBD that affected Recalled Devices, that the Recalled Devices posed serious risks to patients, that St. Jude allegedly misrepresented these risks to the FDA, or that the Government had paid for any such devices. In short, publicly disclosed information forms the structural foundation of Burke's action; the details regarding her personal experiences are, by contrast, largely ornamental.

Second, and relatedly, Burke asserts that "[s]imilar to *U.S. ex rel. Sheldon*, the public disclosures here disclose background information such as the battery defect, but do not rise to the level of revealing 'allegations and transactions.'" ECF 39 at 5 (citing *United States ex rel. Sheldon v. Forest Lab'ys, LLC*, 499 F. Supp. 3d 184, 205 (D. Md. 2020)). Burke's reliance on *U.S. ex rel. Sheldon* is misplaced. In that case, the court utilized the D.C. Circuit's guidance for assessing whether information amounts to an "allegation or transaction" for purposes of the FCA:

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

Id. (quoting *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994) (emphasis in original)). Utilizing that formula, this Court is satisfied that public disclosures collectively revealed all essential elements comprising the allegedly fraudulent

transaction.[5] In contrast to the documents in *U.S. ex rel. Sheldon*, which "merely note[d] the various reporting requirements," the public disclosures here revealed transactions sufficient to allow readers to infer that fraud had been committed. *See U.S. ex rel. Springfield Terminal Ry. Co.*, 14 F.3d at 654.

Finally, Burke argues that "not a single other person—including DOJ itself—inferred fraud from that [FDA Notice] recall information." ECF 39 at 8. Even leaving aside the dubiousness of this claim,[6] it remains immaterial. The FCA does not demand that any public disclosure specifically label conduct as fraudulent. *See U.S. ex rel. Hastings v. Wells Fargo Bank, Nat. Ass'n (Inc.)*, 2014 WL 3519129, at *11 (C.D. Cal. July 15, 2014), aff'd sub nom. *United States Hastings v. Wells Fargo Bank, NA, Inc.*, 656 F. App'x 328 (9th Cir. 2016) ("Identifying the legal consequences of information already in the public domain does not constitute discovery of fraud."). Nor is it necessary that the alleged fraud be deducible from any single public disclosure in isolation. *See United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54. (1st Cir. 2009)

[5] As described throughout, specific information in public disclosures revealed that St. Jude instituted a design change to mitigate PBD in May, 2015, ECF 38-5; that it continued to distribute Recalled Devices after May, 2015, ECF 38-6; that its distribution of Recalled Devices persisted until the FDA instituted a Class I recall, *id.*; and that, at the time of the recall, St. Jude had received adverse incident reports regarding the devices for several years, ECF 38-5, ECF 38-8.

[6] At least one of the sources inferred fraudulent conduct on the part of St. Jude. *See* ECF 38-5 (Interviewing a Minneapolis-based cardiologist who stated that St. Jude's conduct "reminded [him] of events a decade ago, when he blew the whistle on Guidant Corp. for making a critical design change to prevent short-circuiting in its Prizm 2 DR defibrillator without telling the medical community."). That episode ultimately culminated in a $30 million settlement to resolve alleged FCA violations. *See Boston Scientific and Subsidiaries to Pay $30 Million for Guidant's Sale of Defective Heart Devices for Use in Medicare Patients*, DEPARTMENT OF JUSTICE (Oct. 7, 2013), https://www.justice.gov/opa/pr/boston-scientific-and-subsidiaries-pay-30-million-guidant-s-sale-defective-heart-devices-use.

("The two states of facts may come from different sources, as long as the disclosures together lead to a plausible inference of fraud.").[7]

In sum, this Court finds that Burke's action is "based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions" in administrative reports and news media. § 3730(d)(1).

ii. Percentage Share

Because Burke's action is based primarily on public disclosures, this Court may award her such sums as it considers appropriate, but not more than 10%. *Id*. In conducting this assessment, this Court must "tak[e] into account the significance of the information and the role of the person bringing the action in advancing the case to litigation." *Id.* Courts frequently look to the legislative history of the FCA, which specifies three factors to guide their analysis: "(1) the significance of the information provided to the government by the *qui tam* plaintiff; (2) the contribution of the *qui tam* plaintiff to the result; and (3) whether the information in the suit provided by the relator was previously known to the government." *U.S. ex rel. Simmons*, 116 F. Supp. at 578.

The first factor—the significance of the information provided—counsels in favor of a minimal award. Burke contributed information showing that a St. Jude sales representative supplied the Recalled Device, which was implanted into her by a healthcare provider who lacked knowledge of its defect. *See* ECF 33-1 at 3-4. The paucity of information provided by Burke is illustrated by comparison to the facts that Burke did not, and could not, provide. For instance,

[7] Similarly, Burke's protestations that certain news articles did not raise an inference of fraud is wholly irrelevant. *See* ECF 39 at 6 ("St Jude stated publicly that it *had not committed* the very conduct that Relator alleged in her Complaint") (emphasis in original); *id.* at 6 n.1 ("Not surprisingly, DOJ does not include these news articles in its list of alleged public disclosures."). There is no requirement that allegations be undisputed, or publicly confirmed by the Defendant itself.

Burke did not contribute any firsthand knowledge regarding flaws in Recalled Devices, alterations in the new battery design, St. Jude's submissions and representations to the FDA, the identities of relevant St. Jude employees, the Government's payment for Recalled Devices, or St. Jude's internal communications, conduct, or knowledge regarding the same.

Burke, for her part, insists that information she provided is significant because "it triggered the government's investigation."[8] ECF 33-1 at 6. This conclusory assertion is minimally persuasive. In contrast to *U.S. ex rel. Simmons*, this Court cannot discern any leads contained in Burke's Complaint that were key to the Government's subsequent investigation of St. Jude but were not otherwise within the public domain. 116 F. Supp. 3d at 578 (relator, a company insider, triggered the government's investigation where he provided written disclosures of evidence, and company documents, which he obtained through his colleague, who in turn possessed firsthand knowledge of the alleged scheme). Nonetheless, this Court is cognizant that Burke's Complaint described a definitive instance in which St. Jude had supplied a Recalled Device to be implanted into a patient more than a year after implementing its new battery design, and mere weeks before the recall was initiated. *See* ECF 1. Accordingly, information in Burke's Complaint is significant

[8] The Government cites a bevy of out-of-circuit caselaw for the proposition that courts have routinely rejected this catalyst theory of recovery. ECF 38 at 29 (collecting cases). The cases marshalled by the Government, however, rejected the catalyst theory in different contexts. *See United States ex rel. Hays v. Hoffman*, 325 F.3d 982, 990 (8th Cir. 2003) (considering original source exception to public disclosure bar); *United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.*, 2007 U.S. Dist. LEXIS 73376, at *30 (E.D. Ark. Sept. 28, 2007) (same); *United States ex rel. Findley v. FPCBoron Employees' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997) (same); *United States v. Fata*, 2019 U.S. Dist. LEXIS 211213, at *8 (E.D. Mich. Dec. 9, 2019) (considering relator's entitlement to a share of separate claim not included in relator's *qui tam* complaint); *United States ex rel. Rille v. PriceWaterhouseCoopers LLP*, 803 F.3d 368, 374 (8th Cir. 2015) (en banc) (same). When considering the significance of a relator's information for purposes of awarding percentage shares under § 3730(d)(1), however, courts in this district have properly considered a relator's role in triggering the investigation. *See, e.g., U.S. ex rel. Simmons*, 116 F. Supp. 3d at 578.

insofar as it supplied an additional data point undergirding, and serving as the ultimate vehicle for, the Government's investigation of, and eventual settlement with, St. Jude. Much like the 15% "finder's fee" for awards within the 15%-25% range, this Court is inclined to credit Burke, at least in part, for compiling the information that spurred, to some degree, the Government's investigation of St. Jude's conduct. *See U.S. ex rel. Simmons*, 116 F. Supp. 3d at 578 ("This 15% 'incentive compensation' is paid to a relator 'even if that person does nothing more than file the action in federal court.'" (quoting *U.S. ex rel. Alderson*, 171 F. Supp. 2d at 1332 n.29 (internal quotation marks omitted)).

The second factor, "the contribution of the *qui tam* plaintiff to the result" also militates in favor of a nominal award. Burke asserts that she assisted the case by filing the action and humanizing the issue. *See* ECF 33-1 at 6 ("Burke contributed to the investigation by personally researching her device, communicating with her surgeon to uncover that it was not an inventory error, and quickly filing this action, providing everything she knew to DOJ. As a victim of the fraud scheme, she provided a sympathetic face to the allegations and humanized the problem."). Burke further notes that her "counsel supported and cooperated with the Government during the entire proceeding." *Id.* at 8. By contrast, the Government asserts that Burke made no contribution to the action and its ultimate resolution. ECF 38 at 32 ("The relator provided no non-public documents (other than information about her own surgery), did not provide names of any witnesses (except her own surgeon), did not review any documents the Government obtained from St. Jude during the investigation, and had no expertise or other unique perspective to provide the Government. Nor did the Government seek any information from the relator in connection with its investigation."). Burke's contribution to the resolution of the case, or "the role of the person bringing the action in advancing the case to litigation," appears to have been just that: bringing the

initial action. § 3730(d)(1). Burke does not appear to have participated in any cognizable manner to the resolution of the case such that she is entitled to a substantial share of its proceeds. Nor does she receive credit for unsolicited and unaccepted willingness to contribute. *See U.S. ex rel. Simmons*, 116 F. Supp. at 579 ("[Relator] is not entitled to a greater share of the settlement for help that [s]he wanted or 'offered' to contribute; the relevant factor considers the help [s]he did contribute.").

The third factor, "whether the information provided was new to the government or was previously known" also counsels in favor of a minimal share. Burke contends that "[w]hile the Government was certainly aware that St. Jude had manufactured defective devices, there is no evidence that the government was aware that St. Jude was still actively selling and implanting these devices more than sixteen months later . . ."). ECF 33-1 at 7. This contention, however, is belied by the FDA Notice itself, which extended its recall to devices distributed until October 2016, nearly two years after the FDA approved St. Jude's new battery design. *See* ECF 38-6. Indeed, not only was information provided by Burke known to the Government, it was publicly disclosed by the Government, through the FDA.

Simply put, Burke's action was primarily derived from specific information contained within public disclosures; she did not provide facts that were significant, or previously unknown to the Government, nor did she otherwise meaningfully contribute to the resolution of the case. Burke did, however, file her *qui tam* Complaint in federal court, alleging FCA violations that arguably launched the Government's investigation into, and favorable settlement with, St. Jude. Under these facts, this Court concludes that she is entitled to a nominal percentage share of the settlement proceeds.

IV. CONCLUSION

For the reasons set forth above, Burke's Motion for Award of Relator's Share, ECF 33, is GRANTED in part and DENIED in part. Burke shall receive 0.5% of $27,000,000—or $135,000—from the proceeds of the Government's settlement of the claim with St. Jude. A separate Order follows.

Dated: December 29, 2021

/s/
Stephanie A. Gallagher
United States District Judge